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09/977,154	10/12/2001	Hugh S. West JR.	14000.11	3848

7590

12/29/2003

John M. Gynn
WORKMAN, NYDEGGER & SEELEY
1000 Eagle Gate Tower
60 East South Temple
Salt Lake City, UT 84111

EXAMINER

RAMANA, ANURADHA

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,154

Applicant(s)

WEST, HUGH S.

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20, 21 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-17, 20, 21 and 23-25 is/are rejected.
- 7) ☒ Claim(s) 7 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/12/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Objections

Claims 1, 7 and 18 are objected to because of the following informalities.

In claim 1 it is suggested that "an angled face" be replaced with "an angled proximal end" for clarity.

In claims 7 and 18, it is suggested "face (all occurrences)" be replaced with "proximal end" for clarity.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-6, 11, 17, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Harle (US 5,653,710).

Harle discloses a screw 101 with a proximal threaded section having an average diameter which is constant over at least one pitch of the thread, an angled face 115' with an angle relative to the central axis in a range of about 10° to about 80°, a distal threaded section having a constant diameter that is less than an average diameter of the proximal threaded section and a single continuous thread 105 of uniform pitch extending between the proximal and distal ends (Fig. 5, col. 9, lines 58-67 and col. 10, lines 1-9).

The initial statement of intended use and all other functional implications related thereto have been considered but do not appear to impose any patentably distinguishing structure over that disclosed by Harle.

Claims 1-4 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Pennig (US 5,536,127).

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Pennig discloses a screw 1 with a proximal threaded section, a distal threaded section having a constant diameter that is less than the average diameter of the proximal threaded section, and a transition section 3 separating the proximal and distal threaded sections wherein the pitch of the proximal threads 4 and the distal threads 4' is the same and the proximal thread has a face inclined to the central axis at an angle of about 10° to about 80°. Pennig also discloses that the screw head has a socket 9 for engagement by a wrench or a driver (Figure 1 and col. 2, lines 33-57).

The initial statement of intended use and all other functional implications related thereto have been considered but do not appear to impose any patentably distinguishing structure over that disclosed by Harle.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Devas (US 4,059,102).

Devas discloses a screw 10 with a proximal threaded section 12, a distal threaded section 11, the distal threaded section having a constant diameter less than the average diameter of the proximal threaded section and a threaded and tapered transition section between the proximal and the distal threaded sections, and a tapered end disposed between the distal threaded section and the distal end that facilitates insertion of the screw 10 (Fig. 1 and col. 2, lines 10-18).

The initial statement of intended use and all other functional implications related thereto have been considered but do not appear to impose any patentably distinguishing structure over that disclosed by Devas.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 2, 8-9, 12-16 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harle (US 5,653,710).

Regarding claim 2, Harle discloses that screw 101 has a part 115" with an external surface 118 which can be engaged by a tool for extraction of screw 101.

Harle discloses another embodiment wherein part 15 (corresponding to 115") has an appropriate internal or external surface for extraction of the screw (col. 7, lines 48-67). Harle also discloses a socket or recess 14 in member 1 that can receive a suitable tool for extraction of the screw (Figure 1, col. 7, lines 39-47 and lines 59-67).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a slot in part 115" for extraction of screw 101. It would have been obvious to one of ordinary skill in the art to substitute a slot for the polygonal external surface 118 wherein so doing would amount to mere substitution of one functionally equivalent structure for another within the same art and the selection of any of these structures would work equally well in the claimed device.

Regarding claims 8 and 9, Harle does not specifically disclose that the face has an angle in a range of about 20° to about 60° or 30° to about 40°.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the face with an angle in a range of about 20° to about 60° or 30° to about 40°, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claim 13, Harle discloses that screw 101 can be made of a metallic or other suitable material (col. 13, lines 28-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made screw 101 of stainless steel or titanium or poly-L-lactic acid, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, namely insertion in a human body, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claims 12, 14, 15, 16 and 23, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made screw 101 with

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the claimed diameters of the proximal and distal portions and the claimed overall lengths, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 8-9, 13-16 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pennig (US 5,536,127).

Regarding claims 8 and 9, Pennig does not specifically disclose that the face has an angle in a range of about 20° to about 60° or 30° to about 40°.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the face with an angle in a range of about 20° to about 60° or 30° to about 40°, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claim 13, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made screw 1 of stainless steel or titanium or poly-l-lactic acid, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, namely insertion in a human body, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claims 14, 15, 16 and 23, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made screw 1 with the claimed diameters of the proximal and distal portions and the claimed overall lengths, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rego, Jr. et al. (US 5,364,400).

Rego, Jr. et al. disclose an interference screw 140 having an overall length of 20 mm or 30 mm and portions of varying diameter for insertion into a bone tunnel. Rego, Jr.

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et al. further disclose forming a tunnel in the bone and inserting the interference screw in the tunnel (Figure 7, col. 2, lines 35-50, col. 3, lines 15-27, col. 4, lines 66-68 and col. 5, lines 1-13).

Although Rego, Jr. et al. does not disclose the length of the interference screw to be in a range of 35 mm to 40 mm, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the interference screw 10 with a length in a range of about 35 mm to 40 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

The claimed method steps are inherently performed by the Rego, Jr. et al. interference screw for the purpose of securing tissue within a bone tunnel.

Response to Arguments

Applicant's arguments with respect to claims 1-6, 8-17, 20-21 and 23-25, Paper No. 7 under "REMARKS," filed on September 29, 2003, have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:30 am and 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR *Anunadha Ramana*
December 26, 2003

Pedro Philogene
PEDRO PHILOGENE
PRIMARY EXAMINER